IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Rogiola

PRODUCT SUMMARY

EU Procedure number	IE/V/0785/004/DC
Name, strength and pharmaceutical form	Rogiola 40 mg chewable tablets for dogs
Active substance(s)	Robenacoxib
Applicant	Krka, d.d. Novo mesto
Legal basis of application	Generic application in accordance with Article 18 of Regulation (EU) 2019/6
Date of Authorisation	31/05/2023
Target species	Dogs
Indication for use	For the treatment of pain and inflammation associated with chronic osteoarthritis. For the treatment of pain and inflammation associated with soft tissue surgery.
ATC vet code	QM01AH91
Concerned Member States	AT, BE, CY, DE, DK, EL, ES, FI, FR, IT, NL, NO, PT, SE

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in relevant articles of Regulation (EU) 2019/6. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the reactions observed are indicated in the SPC.
The product is safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 40 mg robenacoxib and the excipients cellulose microcrystalline, povidone, crospovidone, yeast powder, meat flavour, silica colloidal anyhdrous and magnesium stearate.
The container/closure system consists of OPA/Al/PVC/Aluminium perforated blister containing 10 tablets: 10 x 1, 30 x 1 or 60 x 1 chewable tablet in perforated unit dose blisters, in a cardboard box.
The choice of the formulation is justified.
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.
Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials
The active substance is Robenacoxib, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.
The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.
There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on Intermediate Products
Not applicable.

E. Control Tests on the Finished Product
The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.
Satisfactory validation data for the analytical methods has been provided.
Batch analytical data from the proposed production sites has been provided demonstrating compliance with the specification.

F. Stability
Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.
Stability data on the finished product has been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information
Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6.
The applicant has cited a suitable reference product, 'Onsior tablets for dogs' which has been authorised for in excess of ten years, and can be accepted as a valid reference product in this generic application. The applicant has demonstrated bioequivalence with the reference product by means of an *in vivo* bioequivalence study, and relevant *in vitro* dissolution tests.
As bioequivalence with a suitable reference product has been accepted, the results of safety tests are not required. The safety aspects of this product are considered to be the same as the reference product.
Warnings and precautions as listed on the product literature are similar to those of the reference product and are adequate to ensure safety of the product to users and the environment.

III.A Safety Testing

Pharmacological Studies
The applicant provided a GLP-compliant pivotal *in vivo* bioequivalence study in which bioequivalence between the candidate product and the reference product, Onsior 20 mg tablets for dogs was investigated. Plasma concentrations of robenacoxib were measured following single administration of the candidate and reference formulations to dogs by the oral route, with blood samples collected at appropriate timepoints.
In dogs, following administration of one 20 mg candidate formulation tablet (1 - 2 mg/kg), maximum plasma concentrations of 2179.92 ng/ml (mean C_{max}) were reached at 0.75 hours (median $T_{max,}$).
From the results of the bioequivalence study conducted and the subsequent statistical analysis, it is accepted that the candidate product formulation is bioequivalent to the reference product formulation in the target species dogs.
Additionally, the applicant provided the results of *in-vitro* dissolution studies, which indicate that the candidate product formulation has a similar dissolution profile to the reference product formulation allowing the extrapolation of *in vivo* study data concerning the 20 mg tablet strength to other tablet strengths in the product range.

Toxicological Studies
No toxicological study data were presented. Given the legal basis of this application, and accepted bioequivalence with the reference product, omission of these data was accepted.

User Safety

The applicant provided a user safety assessment in compliance with the relevant guideline. The following user safety warnings are included in the SPC:

For pregnant women, particularly near-term pregnant women, prolonged dermal exposure increases the risk of premature closure of the ductus arteriosus in the foetus. Pregnant women should take special care to avoid accidental exposure.
Accidental ingestion increases the risk for NSAID adverse effects, particularly in small children. Care should be taken to avoid accidental ingestion by children. In order to prevent children from accessing the product, do not remove tablets from the blister until ready to administer to the animal. Tablets should be administered and stored (in the original packaging) out of sight and reach of children.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use of the veterinary medicinal product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment
Phase I
The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the product will be used in the target animal species dogs (a non-food producing companion animal species).

III. SAFETY ASSESSMENT

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies
As this is a generic application according to Article 18 of Regulation (EU) 2019/6, and bioequivalence with a reference product has been accepted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.